

SEP - 2 2003

K030633

page 1/2

**510(k) Summary for the Medtronic AVE Bridge Constant
Biliary Stent System**

**510(k)
Summary** This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.

Submitter
807.92(a)(1) Medtronic AVE, Inc.
Peripheral Technologies
3576 Unocal Place
Santa Rosa, California 95403

Contact Person
807.92(a)(1) Sarah Sheppard
Associate Product Regulation Manager
Phone: (707) 591-7465
Fax: (707) 591-7406
E-mail: sarah.sheppard@medtronic.com

Date Prepared
807.92(a)(1) February 26, 2003 / Name change notification: April 8th, 2003

Trade Name
807.92(a)(2) Medtronic AVE Bridge Constant Biliary Stent System per 807.92 (a) (2)

Common Name
807.92(a)(2) Biliary Stent and Delivery System

Classification Name
807.92(a)(2) Biliary Catheter and Accessories

**Device
Classification**
807.92(a)(2) Classification: Class II
Classification Panel: 78FGE
Regulation Number: 21 C.F.R. §876.5010

Predicate Device
807.92(a)(3) Bridge Extra Support (K991533) cleared July 29th, 1999
Bridge Assurant (K011817) cleared August 22nd, 2001

**Performance
Standards** Performance standards have not been established by the FDA under section 514 of the Federal, Food, Drug and Cosmetic Act

K030633

510(k) Summary for the Medtronic AVE Bridge Constant Biliary Stent System

Device Description 807.92(a)(4)	The subject device is a single use only device with a stent mounted on an over-the-wire delivery system. The device is equipped with an AV100 balloon mounted on the distal portion of the catheter to facilitate the percutaneous delivery of the stent.
Indications for Use 807.92(a)(5)	The Bridge Constant Biliary Stent System is indicated for use in the palliation of malignant neoplasm in the biliary tree.
Technological Characteristics 807.92(a)(6)	The Bridge Constant is substantially equivalent to the currently marketed Bridge Extra Support (K991533) and Bridge Assurant (K011817) devices. The subject and predicate devices are technologically similar and are intended for palliation of malignant neoplasms in the biliary tree. The subject and predicate devices are constructed of biocompatible materials. The subject and predicate devices are both balloon expandable and feature stents pre-mounted on a sheathless stent delivery system. The subject and predicate devices are comparable and are intended to meet clinical needs. The difference between the subject and predicate devices are not relevant to the ability of the subject device to palliate malignant neoplasms in the biliary tree.
Nonclinical Performance 807.92(b)(1)	Preclinical/in-vitro testing was conducted to confirm the safe and effective performance of this device as well as the biocompatibility of the device.
Sterilization 807.92(b)(1)	The Bridge Constant Biliary Stent System is provided sterile. The device is not intended for reuse or resterilization.
Conclusion 807.92(b)(3)	The Bridge Constant Biliary Stent System is substantially equivalent to the currently cleared and marketed devices (Bridge Extra Support – K991533 and Bridge Assurant – K011817) and meets the clinical needs of the physicians.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2003

Ms. Sarah Sheppard
Associate Product Regulation Manager
Medtronic AVE
3576 Unocal Place
SANTA ROSA CA 95403

Re: K030633

Trade/Device Name: Medtronic AVE Bridge Constant Biliary Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: June 3, 2003
Received: June 4, 2003

Dear Ms. Sheppard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

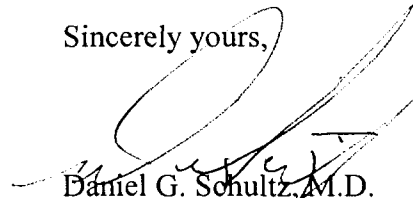
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Daniel G. Schultz, M.D.

Director

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K030633

Device Name: Medtronic AVE Bridge Constant Biliary Stent System

FDA's Statement of the Indications For Use for device:

The Medtronic AVE Bridge Constant Biliary Stent System is indicated for use in the palliation of malignant neoplasms in the biliary tree.

Prescription Use ☒ OR Over-The-Counter Use ☐
(Per 21 CFR 801.109)

Nancy C. Brogden
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030633